

### **REMARKS/ARGUMENTS**

Claims 33-46 are currently pending in the present application. Claims 1-32 are cancelled or were previously canceled, without prejudice or disclaimer. Claims 33-46 have been added.

Claim 33 has been written to recite “a bone-growth-initiating substance or bone-growth-stimulating substance” for minor editorial purposes.

Claim 33 also recites that these substances are of the “superfamily TGF- $\beta$ .”

The new claims are supported by the claims and specification, as originally filed, e.g., at page 4 lines 1-6, page 8, lines 18-25, page 9, lines 18-23, page 12, lines 17-21, and original claims 1-28. No new matter has been added.

Reconsideration of the application and entry of the amendments is respectfully requested in view of the following remarks.

### **Election/Restriction**

The restriction of claim 32, as indicated in the present Office Action as not elected by original presentation, is respectfully traversed. According to the Office, the “elected claims were to implant material” and “hole implant claims were not elected.” Present Office Action at pages 2 to 3.

Claim 32 is now re-represented as new claims 40 and 46. Applicants point out that that claim 32 (i.e., new claims 40 and 46) was not the same and did not include all of the components of non-elected/cancelled claims 11-15 (reciting an implant for application in a hole formed in tissue and/or bone). It is further noted that claim 32 depended from claim 22 (an implant), in which the claimed dental implant included all of the implant material components/limitations of claim 32. Similarly, new claims 40 and 46 depend, directly or indirectly, from claim 33, and include all of the limitations of new claim 33. Therefore, a search, consideration, and examination of new claims 40 and 46 would not be a burden on the Office. Accordingly, consideration and examination of new claims 40 and 46 is requested.

**Rejection under 35 U.S.C. § 103(a)**

The rejection of claims 22-23, 25, and 29-31 under 35 U.S.C. § 103(a) as obvious over Hunter et al. (U.S. Patent No. 6,447,550) is respectfully traversed for reasons of record and the additional reasons below.

As indicated above, claim 22 has been canceled. Claim 33 has been added, which recites:

An implant comprising:

titanium and having one or more surfaces which can be applied in or on tissue areas and/or bone growth areas, one or more of the said surfaces being arranged with a depot for a bone-growth-initiating **substance** or bone-growth-stimulating substance of the **superfamily TGF- $\beta$** ,

wherein the depot is formed by a pore arrangement in a relatively thick oxide layer on the titanium, and

wherein the oxide layer has a thickness in the range of 1-20  $\mu\text{m}$ .

(Emphasis added).

In particular, as described in the present specification, the surface (pore arrangement) of the implant functions as a depot for bone-growth- initiating and/or bone-growth-stimulating substances, i.e., bone matrix proteins of the superfamily TGF- $\beta$ . When the depot is filled with the substance and the implant is in position in the hole, a release function for releasing the substance to the surrounding tissue or bone comes into operation. As a result of the depot, the delivery and release of the proteins can be controlled. *See* present specification at page 12, lines 17-35.

By contrast, Hunter et al. merely describes oxide coated orthopedic implants or prostheses fabricated of zirconium or zirconium containing metal alloys, or a thin coating of zirconium or zirconium alloy on conventional orthopedic implant materials. *See* Abstract.

As pointed out by the Office at page 4 of the Office Action, the reference describes the formation of an oxide layer with a specific thickness range at columns 6 to 7. The Office also acknowledges that Hunter does not expressly disclose that any oxide layer described in the reference is highly porous, with  $1 \times 10^7 - 1 \times 10^{10}$  pores/cm<sup>2</sup>, as now recited in depend claim 35. According to the Office, the presently claimed high porosity would be an obvious extension

of the prior art teachings. Present Office Action at page 4.

Contrary to the Office's assertion, the references mentions that it is desirable to *polish* the oxide surface to obtain a smooth finish, since the implants are subject to wear. *See e.g.*, col. 7, lines 37 to 43 and Applicants' Response filed October 1, 2008. The reference further indicates that an alloy may be used to provide a porous bead or wire mesh surface, and that such porous coatings can be treated by oxidation. Col. 7, lines 49-54. However, there is no indication that the oxidized layer is porous or any guidance for the formation of the claimed pore arrangement, or any description/objective of an oxide layer functioning as a depot for bone-growth- initiating and/or bone-growth-stimulating substances. Further, there is no indication that one would modify the reference to include a depot as presently claimed. *See Takeda Chem. Indus., v. Alphapharm Pty. Ltd.*, 492 F.3d 1350, 1356-57 (Fed. Cir. 2007) (emphasizing that there must be some identified reason that would have "prompted" a chemist to make a modification in a particular manner to establish *prima facie* obviousness). Therefore, the claimed implant is clearly unobvious over the reference.

Applicants also point out, as argued in the Response filed October 1, 2008, that Hunter et al. specifically describes that the thickness of its *dense* oxide layer, and not porosity, is the ideal feature of the coating layer. *See* col. 6, lines 4-10. In fact, "[l]onger oxidation times and higher oxidation temperatures will increase this thickness, but may compromise coating integrity." Col. 7, lines 8-10. Therefore, the *high* porosity or that a specific porosity of claimed invention clearly is not suggested or would be an obvious extension of the reference.

Applicants further note that the Office has indicated in the rejection that the "bone-growth-stimulating substance" is a "non-elected member of this Markush group." However, Applicants submit that there was no prior restriction/election made regarding either the substance. Further, it is understood, as provided in amended new claim 33 and throughout the specification, that the substances may function in the same manner, in which they are both of the superfamily TGF- $\beta$ .

Accordingly, withdrawal of the rejection and consideration of the new claims is requested.

**Rejection for Obviousness-Type Double Patenting**

Applicants thank the Examiner for indicating that the rejection of claims 1-6, 9 and 22 over claims 1-3, 5 and 8 of U.S. Patent No. 7,048,541 has been withdrawn, and that the remaining double patenting rejections over copending applications 10/482,727 and 10/482,737 have been held in abeyance.

Applicants believe no fees are due with this response. However, if any additional fees are due, please charge our Deposit Account No. 22-0185, under Order No. 21547-00286-US from which the undersigned is authorized to draw.

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Respectfully submitted,

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